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Fax Cover Sheet

Date: 1/23/2007

To: David C. Thomas, Patent Examiner 571-272-
3320

From: Mark Farrell (LEE & HAYES, pllc)

Re: App No. 10 / 731,419

Phone: (509) 324-9256

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Number of Pages including cover sheet: 3

Hi Examiner Thomas!

Can we schedule a phone call / Examiner interview?

Thanks,

-Mark

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PTOL-413A (09-04)

Approved for use through 07/31/2008. OMB 0851-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Applicant Initiated Interview Request Form

Application No.: 10/731,419 First Named Applicant: BASSEM A. BEJJANI
 Examiner: DAVID C THOMAS Art Unit: 1637 Status of Application: A/E

Tentative Participants:

(1) DAVID THOMAS - EXAMINER (2) MARK FARRELL - APPLICANT'S COUNSEL

(3) _____ (4) _____

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Proposed Date of Interview: before Jan 27, 07? Proposed Time: _____ (AM/PM)

Type of Interview Requested:

(1) ☒ Telephonic (2) ☐ Personal (3) ☐ Video Conference

Exhibit To Be Shown or Demonstrated: ☒ YES ☐ NO

If yes, provide brief description: See next page.

Issues To Be Discussed

Issues (Rej., Obj., etc)	Claims/ Fig. #s	Prior Art	Discussed	Agreed	Not Agreed
(1) <u>Rej § 102</u>	<u>1</u>	<u>CHENCHIK GORDON</u>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(2) _____	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(3) _____	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(4) _____	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Continuation Sheet Attached					

Brief Description of Arguments to be Presented:

See next page. Chenchik ref. is not in same field. Applicants know the inventor of the GORDON ref. (Joan GORDON; Clark RUSSELL) these people do not think the GORDON ref. reads on Applicants' claims. The molecular bio community is about to publish Applicants' technique - after the Gordon inventors just asked Applicants for a summary paragraph.
 An interview was conducted on the above-identified application on _____

NOTE: This form should be completed by applicant and submitted to the examiner in advance of the interview (see MPEP § 713.01).

This application will not be delayed from issue because of applicant's failure to submit a written record of this interview. Therefore, applicant is advised to file a statement of the substance of this interview (37 CFR 1.133(b)) as soon as possible.

Applicant/Applicant's Representative Signature

Examiner/SPE Signature

MARK C. FARRELL
 Typed/Printed Name of Applicant or Representative

45,988
 Registration Number, if applicable

This collection of information is required by 37 CFR 1.133. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO in process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 21 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450, DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

RE: EXAMINER INTERVIEW

10/731,419

Gordon Response:

Claim 1 of our methodology does not require the use of vectors or any double stranded constructs. Our invention employs a mix of single stranded oligonucleotides that are able to be exponentially amplified directly (starting from single stranded fragments) using one single primer pair to amplify every fragment in the control mixture which may or may not be included in the control mix. By varying the concentration of each reference oligonucleotide or primer pair, we are able to modulate amplification of all of the differing control oligonucleotides that when used in a test method will produce a standardized mix of PCR amplicons for all mutations of interest. This is beyond the scope of the Gordon patent. The Gordon patent refers to producing double stranded DNA products and primarily deals with utilizing primers specific to each cassette fragment to generate an appropriate level of PCR amplicon to be used for cloning methods to generate each cassette. While both methods employ the use of primers and PCR amplification, the design and application of these methods are used in a manner to produce fundamentally different results at completely different stages. The purpose of the Gordon methodology, in reference to introduced PCR primer sites, is to produce a pure (cassette specific) collection of double stranded fragments for each single cassette that will eventually be used for digestion and subsequent ligation 5' to 3' into a construct containing a vector. The added primer sites introduce restriction sites for subsequent cloning experiments and this is a common practice and not novel. The constructs carrying one or more of these "cassettes" in a vector comprise a finished control product as explained in the Gordon patent. The artificial primer sites that were introduced for generating "cassettes" are not used in ways beyond those illustrated above or in the downstream testing or additional amplification of these cassettes by the test methods for which these controls are designed. The Gordon methodology generates double stranded fragments that are then ligated into a vector to produce a single control molecule carrying multiple mutations "in series". Our methodology produces small fragments that are single stranded and amplify exponentially by either an internal or external primer pair based on the design of the artificial tags introduced at the 5' and 3' end of each fragment. Our control carries multiple control molecules "in parallel" which is not anticipated by Gordon.

Hi Examiner Thomas,

The GORDON reference inventors regard applicants' subject matter as novel, (Applicants and Gordon inventors, of course, know each other.) The molecular bio community regards applicants' subject matter as novel -- and about to be published too.

- Mark Jamell
45,988

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